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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,824	09/18/98	ENDL J	P564-7029

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	12

DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/981,824	Endl et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Jun 29, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-3 and 5-52* is/are pending in the applicat

Of the above, claim(s) *6-17 and 21-52* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 5, and 18-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *10*, filed 3/29/01

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed 6/29/00 is acknowledged and has been entered.

Claims 1-3 and 5-52 are pending.

Claims 6 (non-elected species of Group I), 7-17 and 21-51 stand withdrawn from further consideration by the examiner, 37 drawn to non-elected inventions.

Claims 1-3, 5 and 18-20 are currently being examined.

The search has been extended to cover a derivative comprising partial regions of the elected species, SEQ ID NO: 7. Claims 18-20 are being examined only as they read on the elected species of peptide and peptide derivative.

2. Regarding Applicant's comments on pages 5 and 6 of said amendment with reference to the restriction requirement, the Applicant's invention does not provide a contribution over the prior art, i.e., a special technical feature, as evidenced in the art rejections that follow.

3. The reference "AG" crossed out in the Form 1449 filed 3/29/99 has not been considered because a translation has not been provided. The sequence information in said reference has not been considered because it is not legible.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 18-20 are indefinite for depending upon canceled claim 4.

b. Claim 1 is indefinite in the recitation of "essentially equivalent" because it is not clear what essentially equivalent specificity or/and affinity of binding to MHC molecules is. The metes and bounds of the claimed invention are not clear.

c. Claim 1 is indefinite in the recitation of "partial regions" and "amino acid sequences" recited in (h) and (I) because these phrases should be recited in the singular.

7. Claims 18-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claims 1-3, 5, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Clare-Salzler et al (WO 95/07992).

Clare-Salzler et al teach two peptides of length 20 amino acid residues which comprise partial regions of the amino acid sequence of the elected species, SEQ ID NO: 7, FFRMVISNPAATHQDIDFLI. The sequences of the reference peptides are VNFFRMVISNPAATHQDIDF and ATHQDIDFLIEEIERLGQDL (claims 1, 15, 17, 36 of the reference), the portions underlined are the portions which consist of partial regions of SEQ ID NO: 7. Said peptides are at least 6 amino acid residues and less than 25 amino acid residues in length. The reference peptides are also amino acid sequences which have an essentially equivalent specificity and/or affinity of binding to MHC molecules as SEQ ID NO: 7 of the instant application. Instant claim 5 is included because the peptide comprises a label, for instance, a radioisotope, a drug, a lectin or a toxin (claims 26 and 27 of the reference). Instant claim 18 is included because the said peptides are used to treat GAD-related autoimmune disorders such as IDDM or stiff man disease. Claim 19 is included because preparations of GAD polypeptides include oil, i.e., an adjuvant or accessory stimulating component (especially page 27 at lines 25-36). The reference peptides are also amino acid sequences which have an essentially equivalent specificity and/or affinity of binding to MHC molecules as SEQ ID NO: 7 of the instant application.

The reference teachings anticipate the claimed invention.

10. Claims 1-3, 5, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,011,139.

Patent No. 6,011,139 discloses a peptide of length 20 amino acid residues which comprises a partial region of the amino acid sequence of the elected species, SEQ ID NO: 7, FFRMVISNPAATHQDIDFLI. The sequence of the reference peptide is VNFFRMVISNPAATHQDIDF (SEQ ID NO: 50 of the reference), the portion underlined is the portion which consists of a partial region of SEQ ID NO: 7. Said peptide is at least 6 amino acid residues and less than 25 amino acid residues in length. The reference peptide is an amino acid sequence which has an essentially equivalent specificity and/or affinity of binding to MHC molecules as SEQ ID NO: 7 of the instant application. Instant claim 5 is included because the peptide comprises a label, for instance, a radioisotope, a drug, a lectin or a toxin (especially column 9, lines 57-67). Instant claim 18 is included because the said peptide in a pharmaceutical composition is used to treat GAD-related autoimmune disorders such as IDDM (especially column 2, lines 45-50 and Abstract) or for immunization in vivo (especially column 7, lines 9-8). Claim 19 is included because preparations of GAD polypeptides for immunization include adjuvants, including oil, i.e., an adjuvant or accessory stimulating component (especially column 7, lines 15-16 and column 14, lines 57-66).
The reference teachings anticipate the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a)

12. Claims 1-3, 5 and 18-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Clare-Salzler et al (WO 95/07992) or Patent No. 6,011,139 each in view of Burke et al (U.S. Patent No. 5,750,114).

Clare-Salzler et al and Patent No. 6,011,139 have both been discussed supra.

Clare-Salzler et al or Patent No. 6,011,139 do not teach said composition wherein the accessory-stimulating component is a cytokine.

Burke et al teach an HSV polypeptide vaccine which further comprises immunomodulating cytokines such as IL-2 and a pharmaceutically acceptable carrier (especially column 4, lines 7-38).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make a pharmaceutical composition comprising the cytokine of Burke et al and the peptide of Clare-Salzler et al or Patent No. 6,011,139.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because it was well known in the art at the time the invention was made to help elicit an immune response to an administered peptide antigen using a cytokine, and as exemplified by the teaching of Burke et al for the composition comprising a peptide, IL-2 and a pharmaceutically acceptable carrier.

13. SEQ ID NO: 7 appears to be free of the prior art.

14. No claim is allowed.

15. This action is made NON-final.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 08/981,824
Art unit 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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September 29, 2000

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